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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/606,320

06/25/2003

Andre R. Abad

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11/05/2004

ALSTON & BIRD LLP
 PIONEER HI-BRED INTERNATIONAL, INC.
 BANK OF AMERICA PLAZA
 101 SOUTH TYRON STREET, SUITE 4000
 CHARLOTTE, NC 28280-4000

EXAMINER

SAMSON, MARIA TERESA D

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 11/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/606,320

Applicant(s)

ABAD ET AL.

Examiner

Maria Teresa Samson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-56 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-9, drawn to endotoxin comprising at least one engineered cathepsin-sensitive proteolytic site, classified in class 530, subclass 350.
- II. Claims, 10-19, drawn to a method of enhancing pesticidal activity of an endotoxin comprising adding at least one engineered cathepsin-sensitive proteolytic site, classified in class 530, subclass 402.
- III. Claims 20-30, drawn to endotoxin comprising a mutation consisting of at least one proteolytic site, classified in class 530, subclass 350.
- IV. Claims 31-33 and 41-53, drawn to nucleic acid encoding a pesticidal polypeptide, transformed host cells and plants with the DNA molecule, and methods of use to impact an insect pest, classified in class 800, subclass 302.
- V. Claims 34-40, drawn to an isolated pesticidal polypeptide and method of use to impact an insect pest, classified in class 514, subclass 2.
- VI. Claims 54-56, drawn to a method of predicting potential areas for modification in the amino acid sequence of a naturally occurring pesticidal protein, classified 530, subclass 402.

2. The inventions are distinct from each other because:

(A.) Groups I, III and V are independent and distinct. The protein of Group I is an endotoxin which has been modified by engineering at least one cathepsin-sensitive proteolytic

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site. The protein of Group III is also an endotoxin, which has been modified by an alteration of at least one proteolytic site of any kind. The modified endotoxin of Group I has a cathepsin-sensitive proteolytic site(s) whereas the modified endotoxin of Group III does not necessarily have one. Thus, a search on Group III would not necessarily find art on Group I, and the groups are not coextensive.

Group V is drawn to an isolated pesticidal protein and includes pesticidal proteins that do not have a proteolytic site. Thus, a search on Group V would not necessarily find art on Groups I and III, and the groups are not coextensive.

Because of these different modifications incorporated into the unmodified endotoxins, the amino acid sequence of the modified endotoxin of Group I and Group III are different from each other and are different from Group V. Thus, the searches are not coextensive and the prior art that teaches the composition of Group I or Group III would not necessarily find prior art that teaches the compositions of Group V.

(B.) Groups I, III and V are independent and distinct from Group IV. The DNA molecule of Group IV and the proteins of Groups I, III and V are distinct because they are physically and functionally distinct chemical entities. The DNA molecule of Group IV is made up of nucleotides while the proteins of Group I, III and V are composed of amino acids. The search requirement for protein involves both text and amino acid sequence searches while the search for DNA requires only a DNA sequence search. Thus, the searches are not coextensive. A search on Group I or Group III or Group V could not necessarily find prior art on the nucleic acid of Group IV and vice versa.

(C.) Groups II and VI are independent and distinct. The method of Group II and the method of VI have different method steps, different starting materials as well as different end products. The method steps of Group VI include subjecting any naturally occurring pesticidal proteins to proteolytic digestion, assaying the digested pesticidal protein for a change in pesticidal activity, determining one or more proteolytic sites for modification, and modifying the amino acid sequence of the naturally occurring pesticidal protein at one or more proteolytic sites. The method step of Group II only includes modifying the amino acid sequence of any endotoxins. In addition, the method of Group II utilized any naturally occurring pesticidal proteins as the starting material while the method of Group VI utilized any endotoxins as the starting material. Furthermore, the end products of the method of Group II are any modified pesticidal proteins while the end products of the method of Group VI are any endotoxins. Thus, the searches are not coextensive and the prior art that teaches the method of Group II would not necessarily be applicable to the method of Group VI.

(D.) Groups II and VI are unrelated to Group IV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, Groups II and VI are drawn to methods of modifying proteins and Group IV is drawn to the nucleotide sequence of pesticidal proteins and thus the groups have different modes of operation, different functions and different effects. Groups II and VI are methods of enhancing pesticidal activity of pesticidal proteins by modifying their amino acid sequences and the methods do not use the DNA of Group IV. Thus, searches on Groups II and VI are not

coextensive with searches on Group IV and the prior art that teaches the method of Group II or Group VI would not necessarily find prior art on the nucleic acid of Group IV and vice versa.

(E.) Groups I, III and V are independent and distinct from Groups II and VI. Inventions II and VI are related to inventions I, III and V as processes of making and products made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the proteins of Groups I, III and V are not the only products that can be produced by the method of Group II and Group VI. The proteins of Groups I, III and V can be made by modifying the DNA molecule encoding a pesticidal protein and using the modified DNA molecule to produce the modified protein. The searches on Groups I, III and V are not coextensive with searches on Groups II and VI and the prior art that teaches the composition of Groups I, III and V would not necessarily applicable to the method of Groups II and VI.

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds that are unrelated to one another, as are different proteins are structurally distinct chemical compounds that are unrelated to one another. These sequences are thus deemed to normally constitute **independent and distinct** inventions within the meaning of 35 U.S.C. 121. Each sequence requires an independent search of the sequence databases. Absent evidence to the contrary, each such nucleotide is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq (see MPEP 803.04 and 2434).

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Upon election of a Group, Applicant is additionally required to select a single nucleotide sequence and an amino acid sequence for said Group, as appropriate. This requirement is not to be construed as a requirement for an election of species, since each nucleotide and amino acid sequence is not a member of single genus of invention, but constitutes an independent and patentably distinct invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, subject matter and search requirement, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

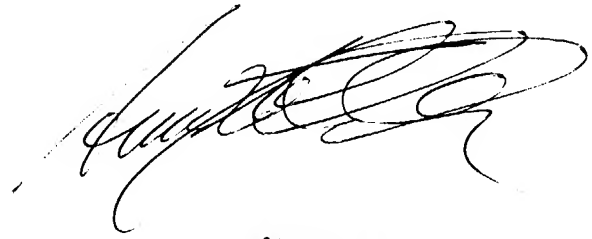
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria Teresa Samson whose telephone number is 571-272-3110. The examiner can normally be reached on 7:00-5:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Maria Teresa Samson, Ph.D
October 28, 2004



**ANNE KUBELIK
PATENT EXAMINER**